# What is the relationship between the intake of cooked dry beans and peas and cardiovascular outcomes?

### Conclusion

There is limited evidence that intake of cooked dry beans and peas lowers serum lipids.

### **Grade: Limited**

Overall strength of the available supporting evidence: Strong; Moderate; Limited; Expert Opinion Only; Grade not assignable For additional information regarding how to interpret grades, click here.

### **Evidence Summary Overview**

Limited evidence exists that dry beans and peas have unique abilities to lower serum lipids; most of the lipid lowering seen in studies is related to the soluble fiber content of these products. The conclusion reached for this question is based on the review of one meta-analysis (Anderson and Major, 2002), five trials (Crujeiras, 2007; Finley, 2007; Pittaway, 2006; Pittaway, 2007; Pittaway, 2008), two prospective cohort studies (Bazzano, 2001; Steffen, 2005), one case-control study (Kabagambe, 2005), and one cross-sectional study (Papanikolaou, 2008). The Committee also considered one randomized crossover trial (Welty, 2007), one prospective cohort study (Kokubo, 2007), and one longitudinal study (Nagata, 2000) regarding soy foods, all published since 2000.

Anderson and Major (2002) quantitatively analyzed changes in serum lipoprotein levels resulting from intake of non-soya pulses. The authors concluded that regular consumption of pulses may have important protective effects on risk for CVD, including decreases in serum cholesterol, low-density lipoprotein cholesterol (LDL-C) and triacylglycerols (TAG) and increases in high-density lipoprotein cholesterol (HDL-C).

In the intervention studies, dry beans and peas lowered serum lipids as expected based on soluble fiber content. In a series of studies including the daily consumption of more than 100g of chickpeas per day for five to 12 weeks, Pittaway et al (2006, 2007, 2008) observed improvements in serum total cholesterol (TC) and LDL-C compared to a control diet without legumes. Similar improvements in TC were observed following an eight-week weight loss intervention that included non-soybean legumes four days each week, and the decrease in TC was directly correlated with increased fiber intake (Crujeiras, 2007).

Bazzano et al (2001) found a strong and independent inverse association between dietary intake of legumes and risk of CHD in the Nutrition Examination Survey Epidemiologic Follow-up Study (NHEFS), which is a prospective cohort study of the First National Health and Nutrition Examination Survey (NHANES I) from 1971 to 1975. Legume consumption four or more times per week compared with less than once a week was associated with a 22% lower risk of coronary heart disease (CHD) and an 11% lower risk of cardiovascular disease (CVD). In the Coronary Artery Risk Development in Young Adults (CARDIA) Study (Steffen, 2005), tertiles of legume intake were less than 0.1, 0.1 to 0.2 and more than 0.2 times per day, supporting extremely low usual intake of legumes. The authors noted that limited consumption of legumes and insufficientstatistical power

precluded definitive conclusions from being drawn about the relationship between intake of legumes and elevated blood pressure (BP). However, it is unclear whether null findings were due to the lack of association or limited range in consumption. In a case-control study in Costa Rica, Kabagambe et al (2005) observed an inverse association between myocardial infarction (MI) and the intake of one serving of beans per day (one third cup of cooked beans) in adjusted analyses. However, no additional benefit was observed with more than one serving per day.

In more than 12 years of follow-up of the Japan Public Health Center-Based Study Cohort I (Kokubo, 2007), investigators saw a decrease in the risk of MI, cerebral infarction and CVD mortality among women consuming soy at least five times per week compared to those consuming soy zero to two times per week. However, no associations were observed for men. In a longitudinal study in Japan, Nagata et al (2000) also observed an inverse correlation between soy product intake and heart disease mortality in women, but not men.

In a randomized crossover trial in which hypertensive, pre-hypertensive and normotensive post-menopausal women consumed the Therapeutic Lifestyle Changes (TLC) diet alone or with 1/2 cup unsalted soy nuts (25 g soy protein) replacing 25g of non-soy protein, benefits to BP and LDL-C were greater for the hypertensive women than the normotensive participants (Welty, 2007).

**Evidence Summary Paragraphs** 

### **Beans and Peas (Not Including Soy)**

### Meta-Analysis

Anderson and Major, 2002 (neutral quality), a meta-analysis of 11 international studies, quantitatively analyzed changes in serum lipoprotein levels resulting from intake of non-soya pulses. Intake of non-soya pulses was associated with decreases in fasting serum cholesterol (-7.2%; 95% CI: -5.8 to -8.6%), LDL-C (-6.2%; 95% CI: -2.8 to -9.5%), TAG (-16.6%; 95% CI: -11.8 to -21.5%) and body weight (-0.9%; 95% CI: 2.2 to -4.1%), as well as an increase in HDL-C (2.6%; 95% CI: 6.3 to -1.0%). The authors concluded that the available evidence indicates that regular consumption of pulses may have important protective effects on risk for CVD.

# **Primary Citations**

### **Trials**

Crujeiras et al, 2007 (neutral quality), a randomized controlled trial (RCT) conducted in Spain, evaluated whether a hypocaloric diet high in non-soybean legumes would decrease oxidative stress in obese subjects in addition to the recognized effects associated with weight loss, especially in relation to lipid peroxidation. Thirty obese subjects (17 men and 13 women) with mean age of 36±8 years and mean body mass index (BMI) of 32.0±5.3kg/m<sup>2</sup> were included in the study. The subjects were randomly assigned to one of two energy-restricted (-30% energy with respect to the subject's energy expenditure) dietary treatments for eight weeks: 1) LD or legume diet with four days a week non-soybean legumes (lentils, chickpeas, peas and fava beans) servings (N=15); 2) CD or control diet group without legume consumption (N=15). The macronutrient content was designed to supply 20% energy from proteins (PRO), 50% from carbohydrates (CHO) and 30% from fat, for both diets. Compliance was assessed with three-day weighted food records. Mean caloric intake was 2,479±1,832 kcal per day at baseline, and 1,462±354kcal per day at the end point (P=0.001). The diets did not have statistical differences in cholesterol content (P=0.641); fiber content in the LD diet was statistically higher than in the CD diet (25±6 vs.18±5g per day; P=0.005). Total plasma cholesterol concentrations decreased in both diets, being significantly different between both diet groups (-14.4±10.6 vs. -3.9±10.7%; P<0.001). The decrease in total cholesterol was directly

correlated with body weight loss (R=0.50; P=0.006) and with increased fiber intake (R=0.44; P=0.022).

**Finley et al, 2007** (positive quality), an RCT conducted in the US, assessed whether pinto bean consumption affects in vitro fecal bacterial fermentation and production of short chain fatty acids, colonic bacterial populations and serum lipids in 40 healthy adults and 40 adults with pre-metabolic syndrome matched for sex and age. After a four-week equilibration period, subjects were randomly assigned to consume a bean entree containing 1/2 cup pinto beans or an isocaloric chicken soup entree daily for 12 weeks. Of the 80 subjects that were randomized, 73 completed the trial (39 males, 34 females, aged 18 to 55 years). Beans lowered serum TC (P<0.014) by approximately 8% in the healthy adults and by 4% in the adults with pre-metabolic syndrome, and lowered serum HDL-C (P<0.05) and LDL-C (P<0.05) in both groups without affecting serum TG, VLDL cholesterol or glucose.

Pittaway et al, 2006 (positive quality), a randomized crossover trial conducted in Australia, compared the effects of a chickpea-supplemented diet and those of a wheat-supplemented diet on serum lipids and lipoproteins. Fifty-two participants enrolled in the trial, and 47 adults completed the study (mean age =  $53.0\pm9.8$  years; mean BMI= $27.6\pm4.1$ kg/m<sup>2</sup>). The chickpea diet involved daily consumption of 140g of canned, drained chickpeas, chickpea bread and chickpea shortbread biscuits provided by the study personnel. The wheat diet involved consumption of whole meal (wheat) bread, high- fiber (wheat) breakfast cereals and shortbread biscuits that participants purchased from their usual grocery store. Both interventions were at least five weeks in duration. There were no significant differences in body weight and BMI between the start and the end of each dietary period or at the end of the two intervention diets (all P>0.2). Serum lipids and lipoproteins were not significantly (NS) different at the start of the intervention diets. Protein (0.9% of energy, P=0.01) and monounsaturated fat (MUFA) (3.3% of total fat, P<0.001) intakes were slightly but significantly lower and the CHO intake significantly higher (1.7% of energy, P<0.001) on the chickpea diet as compared with the wheat diet. Serum TC was 3.9% lower (0.22mmol per L; 95% CI: 0.1, 0.35; P=0.001) and LDL-C was 4.6% lower (0.18mmol per L; 95% CI: 0.07, 0.29; P=0.002) at the completion of the chickpea diet as compared with the wheat diet. Multivariate analyses suggested that the differences in serum lipids were mainly due to small differences in polyunsaturated fatty acid (PUFA) and dietary fiber contents between the two intervention diets. Serum HDL-C and TAG levels were NS different between the two intervention diets. The authors concluded that inclusion of chickpeas in an intervention diet resulted in lower serum total and LDL-C levels as compared with a wheat-supplemented diet.

Pittaway et al, 2007 (positive-quality), a randomized crossover trial conducted in Australia, compared the effects on serum lipids, glucose tolerance, satiety and bowel function of a diet supplemented with chickpeas to a wheat-based diet of similar fiber content, and also the impact of a lower fiber diet on bowel function and satiety. Subjects consumed the two dietary interventions for five weeks each, with a washout period of six to eight weeks between interventions; the additional low fiber diet study was followed for three weeks only. The chickpea diet was based on consuming 140 g of canned, drained chickpeas daily, plus bread and shortbread biscuits made with 30% chickpea flour. The wheat diet was based on consuming whole wheat bread and high fiber breakfast cereals daily, while the lower fiber diet included white bread and lower fiber breakfast cereals. Thirty-one subjects (mean age 50.6±10.5 years) were enrolled in the trial, 27 (17 female, 10 male) completed both diet interventions and 18 (11 female, seven male) completed the lower fiber diet study. Compared to the wheat diet, the chickpea diet resulted in reductions in serum TC of 0.25mmol per L (P<0.01) and LDL-C of 0.20mmol per L (P=0.02), while there were NS differences in glucose tolerance. Some participants reported a perceived improvement in general bowel health and greater satiety during the chickpea diet.

**Pittaway et al, 2008** (positive quality), an ordered crossover trial conducted in Australia, observed the effects of chickpea supplementation on ad libitum nutrient intake, body weight, serum lipids, lipoproteins and other metabolic changes. Subjects consumed normal intake for four weeks, ad libitum diet with at least 104g of chickpeas per day for 12 weeks, and normal intake for four weeks. 50 subjects (mean age 52.2±6.1 years) were enrolled and 45 (13 pre-menopausal women, 19 post-menopausal women and 13 men) completed the trial. During the chickpea phase, mean dietary fiber intake was 6.77g per day higher and mean PUFA consumption was 2.66% higher (P<0.001), causing the polyunsaturated to saturated fatty acids (SFA) ratio to change from 0.39 to 0.47 (P=0.045). Serum TC decreased by 7.7mg per dL (0.20mmol per L) and LDL-C decreased by 7.3mg per dL (0.19mmol per L) after the chickpea phase (both P<0.01). In addition, fasting insulin decreased by 0.75μIU per ml (0.19mmol per L) and the homeostasis assessment model of insulin resistance was decreased by 0.21 (both P=0.01). Dietary fiber had the greatest single effect, reducing serum TC by 15.8mg per dL (0.41mmol per L, P=0.01).

# **Prospective Cohort Studies**

Bazzano et al, 2001 (positive quality), a prospective cohort study in the US, examined the relationship between legume consumption and risk of CHD. Participants were 9,632 subjects from the Nutrition Examination Survey Epidemiologic Follow-up Study (NHEFS), which is a prospective cohort study of NHANES I from 1971 to 1975 and aged 25 to 74 years. Dietary assessment was analyzed using a three-month food-frequency questionnaire (FFQ) with 13 major categories including legume intake. Incidence of CHD and CVD was obtained from medical records and death certificates. Over an average of 19 years of follow-up, 1,802 incident cases of CHD and 3,680 incident cases of CVD were documented. Legume consumption was significantly and inversely associated with risk of CHD (P=0.002 for trend) and CVD (P=0.02 for trend) after adjustment for established CVD risk factors. Legume consumption four times or more per week compared with less than once a week was associated with a 22% lower risk of CHD (RR=0.78; 95% CI: 0.68, 0.90) and an 11% lower risk of CVD (RR=0.89; 95% CI: 0.80, 0.98). The authors concluded that their study reported a strong and independent inverse association between dietary intake of legumes and risk of CHD in a representative sample of the noninstitutionalized adult US population.

Steffen et al, 2005 (positive quality), a prospective cohort study conducted in the US, evaluated associations of dietary intake with the 15-year incidence of elevated blood pressure (EBP) in participants from the Coronary Artery Risk Development in Young Adults (CARDIA) Study. Dietary intake (interviewer-administered diet history) was measured at baseline and year seven, while clinic exams were scheduled at baseline and years two, five, seven, 10 and 15. Out of 5,115 participants (aged 18 to 30 years at baseline) in the original cohort, 4,304 participants were included in the analysis (883 black men, 1,249 black women, 989 white men and 1,183 white women). Over 15 years, 23.2% of study participants experienced incident EBP (defined as incidence SBP higher than 130mmHg, DBP higher than 85mmHg, or the use of antihypertensive medications); 591 (13.7%) had HTN and 406 (9.4%) had high-normal blood pressure. Of those who developed EBP, 64% were black men and women. After adjustment for confounding variables, plant food intake (whole grains, refined grains, fruits, vegetables, nuts and legumes) was inversely related to EBP. Concerning specific plant subgroups, whole grain, fruit and nuts were inversely associated with EBP  $(P \le 0.05)$ , whereas no association was observed with refined grains, vegetables or legumes. Tertiles of legume intake were less than 0.1, 0.1 to 0.2 and more than 0.2 times per day. Hazard ratios for legume intake from tertiles one through three were 1.00, 0.93 (95% CI: 0.80, 1.09), and 0.88 (95% CI: 0.75, 1.03; P=0.11). Authors noted that limited consumption of legumes and insufficient statistical power precluded definitive conclusions from being drawn. It is unclear whether null findings were due to the lack of association or limited range in consumption.

## Case-Control Study

**Kabagambe et al, 2005** (positive quality), a case-control study conducted in Costa Rica, determined whether consumption of dried mature beans, the main legume in Latin America, is associated with MI. A total of 2,119 survivors of a first acute MI (73% male, 27% female, mean age 59±11 years) and 2,119 healthy age-, sex- and area of residence-matched controls (mean age 58±11 years) were included in the analysis. Dietary intake was assessed through FFQs. Compared with non-consumers, intake of one serving of beans per day (1/3 cup of cooked beans) was inversely associated with MI in adjusted analyses (OR=0.62; 95% CI: 0.45, 0.88). However, no additional benefit was observed with more than one serving per day (OR=0.73; 95% CI: 0.52, 1.03).

# Cross-Sectional Study

Papanikolaou et al, 2008 (positive quality), a cross-sectional study in the US, evaluated the association of consuming beans on nutrient intakes and physiological parameters using data from the NHANES 1999 to 2002. A secondary analysis was completed with a reliable 24-hour dietary recall where three groups of bean consumers were identified: 1) Baked bean (BB); 2) Variety bean (VB); and 3) Variety bean or baked bean (VBBB). Adult BB consumers had lower SBP (120.4±1.4 vs. 123.3±0.4mmHg, P=0.019) in comparison to non-consumers. There were NS differences in odds ratios (OR) for most risk factors (elevated blood pressure risk, lower HDL-C, elevated LDL-C, elevated TAG and elevated fasting blood glucose) based on BB consumption. There were also NS differences in odds ratios for most risk factors (elevated DBP, lower HDL-C, elevated LDL-C, elevated TAG, and elevated fasting blood glucose) based on VBBB consumption. However, in 20 to 40 year olds, there was a 47% reduced risk of elevated SBP (OR=0.53; 95% CI: 0.29, 0.96; P=0.037) in VBBB consumers relative to non-consumers. Considering all adults, VBBB consumers had lower SBP relative to non-consumers (121.7±1.1 vs. 123.4±0.4mmHg, P=0.092). In conclusion, bean consumers had better overall nutrient intake levels and lower SBP in comparison to non-consumers.

### **Soy Foods**

### **Trials**

Welty et al, 2007 (neutral quality), a randomized crossover trial conducted in the US, determined the effect of soy nuts on systolic and diastolic blood pressure and lipid levels in hypertensive (SBP higher than 140mmHg), pre-hypertensive (SBP 120 to 139mmHg) and normotensive (SBP lower than 120mmHg) post-menopausal women. After a four-week run-in period, women were randomized to eight weeks of a Therapeutic Lifestyle Changes (TLC) diet alone and eight weeks of a TLC diet of similar energy, fat and protein content in which 1/2 cup unsalted soy nuts (25g soy protein, 101mg aglycone isoflavones) replaced 25g of non-soy protein, with a four-week washout between diets. Sixty women were included in the trial (48 normotensive, mean age 53.5±5.3 years and 12 hypertensive, mean age 58.3±6.5 years). Compared with the TLC diet alone, the TLC diet with soy nuts lowered SBP by 9.9% (P=0.003) and DBP by 6.8% (P=0.001) in hypertensive women, 5.5% (P=0.003) and 2.7% (P=0.18) in pre-hypertensive women, and 4.5% (P=0.003) and 3.0% (P=0.06) in normotensive women. In addition, soy nut supplementation lowered LDL-C by 11% and apolipoprotein B levels by 8% (P=0.04 for both) in hypertensive women but had no effect in normotensive women. No changes in TC, HDL-C, or TG were observed in any group.

### **Prospective Cohort Studies**

**Kokubo et al, 2007** (neutral quality), a prospective cohort study conducted in Japan, identified if the risk of cerebral infarction (CI) and MI was reduced through exposure to a large quantity of isoflavones, using data from the Japan Public Health Center-Based Study Cohort I. Intake of

isoflavones, soy and beans was assessed through FFQs twice during the mean follow-up period of 12.5 years. Of the original cohort of 27,063 men and 27,435 women aged 40 to 59 years at baseline, 40,462 subjects were included in the analysis. During the mean follow-up period of 12.5 years, 587 cases of CI, 308 cases of MI and 232 cases of mortality for CI and MI combined were identified. For women, the multivariate hazard ratios for those consuming soy five or more times per week compared to those consuming soy zero to two times per week was 0.64 (95% CI: 0.43, 0.95; P=0.037) for CI, 0.55 (95% CI: 0.26, 1.09, P=0.098) for MI and 0.71 (95% CI: 0.49, 1.01, P=0.065) for CI and MI combined. No significant association between intake of miso soup or beans with CI or MI was observed among women. For men, there was NS association between dietary intake of soy, miso soup or beans with CI or MI. The multivariable HR for those who consumed soy foods five or more days per week compared with zero to two days per week was 0.31 (95% CI: 0.13, 0.74; P=0.006) for ischemic CVD mortality in women, but no association was found in men. No significant associations between intake of miso soup and beans and ischemic CVD mortality were present in either men or women.

# Longitudinal Study

**Nagata et al, 2000** (neutral quality), a longitudinal study conducted in Japan, examined ecological correlations between soy product intake and mortality rates from several types of cancer and heart disease. Morbidity data were taken from the Special Report on Vital Statistics and Population Census of Japan in 1995 and nutrient intake data were taken from the National Nutritional Survey reports between 1980 and 1985. 6,000 randomly selected households were included in the analysis. An inverse correlation between soy product intake (as total amount) and heart disease mortality was statistically significant in women after controlling for covariates (R=-0.32, P=0.04). No significant association was observed for men.

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Author, Year, Study Design, Class, Rating	Participants	Study Methodology	Outcomes
Anderson JW et al 2002 Study Design: Meta-analysis Class: M Rating:	Meta-analysis of 11 international studies.	Quantitatively analyzed Δs in serum lipoprotein levels resulting from intake of non-soya pulses.	Intake of non-soya pulses was associated with ↓ in fasting serum cholesterol (-7.2%; 95% CI: -5.8 to -8.6%), LDL-C (-6.2%; 95% CI: -2.8 to -9.5%), TAG (-16.6%; 95% CI: -11.8 to -21.5%) and body weight (-0.9%; 95% CI: 2.2 to -4.1%), as well as ↑ in HDL-C (2.6%; 95%
			CI: 6.3 to -1.0%).

N=9,632.Legume intake assessed Bazzano LA, Over an average of 19 years using three-month FFQ. of follow-up, 1,802 incident He J et al, cases of CHD and 3,680 2001 Age: 25 to 74 years. Incidence of CHD and incident cases of CVD were CVD obtained from Study Design: Nutrition Examination documented. **Prospective** Survey Epidemiologic medical records and death Legume Cohort Study Follow-up Study certificates. consumption significantly (NHEFS), which is a and inversely associated Class: B prospective cohort with risk of CHD (P=0.002 study of NHANES I, for trend) and CVD (P=0.02 from 1971 to 1975. Rating: for trend) after adjustment for established CVD risk Location: United factors States. Legume consumption ≥four times per week compared with <once a week was associated with a 22% 1 risk of CHD (RR=0.78; 95% CI: 0.68, 0.90) and an 11% ↓ risk of CVD (RR=0.89; 95% CI: 0.80, 0.98). N=30 obese subjects Intervention: Crujeiras AB, Mean caloric intake Parra D et al, (17 men, 13 women). 2,479±1,832kcal per day at Two energy-restricted 2007 baseline and 1,462±354kcal (-30% energy with respect per day at end point Mean age: 36±8 to subject's energy Study Design: years. (P=0.001). expenditure) dietary Randomized treatments for eight weeks: Diets did not have Controlled Mean BMI: Trial  $32.0\pm 5.3 \text{kg/m}^2$ . statistical differences in 1) LD diet with four days cholesterol content a week non-soybean Class: A Location: Spain. (P=0.641); fiber content legume (lentils, chickpeas, in LD diet statistically \ peas and faba beans) than in CD diet  $(25\pm6)$ Rating: servings (N=15) vs.18 $\pm$ 5g per day; P=0.005). 2) CD or control diet without legume Total plasma cholesterol consumption (N=15). concentrations ↓ in both diets, being significantly Macronutrients content: different between both diet 20% PRO, 50% CHO and groups (-14.4±10.6 vs. 30% fat for both diets. -3.9±10.7%; P<0.001).

		Compliance assessed with three-day weighted food records.	↓ in TC directly correlated with body weight ↓ (R=0.50; P=0.006) and with ↑ fiber intake (R=0.44; P=0.022).
Finley JW et al 2007  Study Design: Randomized Controlled Trial  Class: A  Rating:	N=40 healthy adults and 40 adults with pre-metabolic syndrome matched for sex and age.  Of the 80 subjects that were randomized, 73 completed the trial (39 males, 34 females)  Age: 18 to 55 years.  Location: United States.	Assessed whether pinto bean consumption affects in vitro fecal bacterial fermentation and production of short chain fatty acids, colonic bacterial populations and serum lipids.  After a four-week equilibration period, subjects were randomly assigned to consume a bean entree containing 1/2 cup pinto beans or an isocaloric chicken soup entree daily for 12 weeks.	Beans \$\psi\$ serum TC (P<0.014) by ~8% in healthy adults and by 4% in adults with pre-metabolic syndrome, and \$\psi\$ serum HDL-C (P<0.05) and LDL-C (P<0.05) in both groups without affecting serum TG, VLDL-C or glucose.
Kabagambe EK et al 2005 Study Design: Case-Control Study Class: C Rating:	N=2,119 survivors of a first acute MI (73% male, 27% female, mean age 59±11 years) and 2,119 healthy age-, sex- and area of residence-matched controls (mean age 58±11 years).  Location: Costa Rica.	Determined whether consumption of dried mature beans, the main legume in Latin America, is associated with MI.  Dietary intake assessed through FFQs.	Compared with non-consumers, intake of one serving of beans per day (1/3 cup of cooked beans) was inversely associated with MI in adjusted analyses (OR=0.62; 95% CI: 0.45, 0.88). However, no additional benefit observed with >one serving per day (OR=0.73, 95% CI: 0.52, 1.03).

Kokubo et al 2007

Study Design: Prospective Cohort Study

Class: B

Rating:

Participants from the Japan Public Health Center-Based Study Cohort I.

Of the original cohort of 27,063 men and 27,435 women aged 40 to 59 years at baseline, 40,462 subjects were included in analysis.

Location: Japan.

Identified if risk of cerebral infarction (CI) and MI was \( \psi \) through exposure to a large quantity of isoflavones.

Intake of isoflavones, soy and beans assessed through FFQs twice during mean follow-up period of 12.5 years. During mean follow-up period of 12.5 years, 587 cases of CI, 308 cases of MI and 232 cases of mortality for CI and MI combined were identified.

For women, multivariate HRs for those consuming soy ≥five times per week compared to those consuming soy zero to two times per week was 0.64 (95% CI: 0.43, 0.95; P=0.037) for CI, 0.55 (95% CI: 0.26, 1.09, P=0.098) for MI and 0.71 (95% CI: 0.49, 1.01, P=0.065) for CI and MI combined.

NS association between intake of miso soup or beans with CI or MI observed among women.

For men, NS association between dietary intake of soy, miso soup or beans with CI or MI.

Multivariable HR for those who consumed soy foods ≥ five days per week compared with zero to two days per week was 0.31 (95% CI: 0.13, 0.74; P=0.006) for ischemic CVD mortality in women, but no association found in men.

NS associations between intake of miso soup and beans and ischemic CVD mortality present in either men or women.

Nagata 2000 Study Design: Longitudinal study Class: C Rating:	N=6,000 randomly selected households.  Location: Japan.	Examined ecological correlations between soy product intake and mortality rates from several types of cancer and heart disease.  Morbidity data taken from the Special Report on Vital Statistics and Population Census of Japan in 1995 and nutrient intake data taken from the National Nutritional Survey reports between 1980 and 1985.	An inverse correlation between soy product intake (as total amount) and heart disease mortality was statistically significant in women after controlling for covariates (R=-0.32, P=0.04).  NS association observed for men.
Papanikolaou Y and Fulgoni VL, 2008  Study Design: Cross-Sectional Study  Class: D  Rating:	N=8,229.  Data from the NHANES 1999 to 2000 and NHANES 2001 to 2002.  Location: United States.	Bean consumption defined by 24-hour dietary recall.  Three groups of bean consumers identified:  1) Baked bean (BB)  2) Variety bean (VB)  3) Variety bean and baked bean (VBBB).  Risk factors of interest: BP, LDL-C, FBG, waist size, HDL-C and BMI.	Adult BB consumers had lower SBP (120.4±1.4 vs. 123.3±0.4mmHg, P=0.019) in comparison to non-consumers.  NS differences in OR for most risk factors (↑ BP risk, ↓ HDL-C, ↑ LDL-C, ↑ TAG and ↑ FBG) based on BB consumption.  NS differences in OR for most risk factors (↑ DBP, ↓ HDL-C, ↑ LDL-C, ↑ TAG and ↑ FBG) based on VBBB consumption.  However, in 20- to 40-year-olds, a 47% ↓ risk of ↑ SBP (OR=0.53; 95% CI: 0.29,0.96; P=0.037) in VBBB consumers relative to non-consumers.  Considering all adults, VBBB consumers had ↓ SBP relative to non-consumers (121.7±1.1)

			vs. 123.4±0.4mmHg, P=0.092).
Pittaway et al 2006  Study Design: Randomized, crossover intervention trial  Class: A  Rating:	N=52 participants enrolled. N=47 adults completed study. Mean age: 53.0±9.8 years. Mean BMI: 27.6±4.1kg/m². Location: Australia.	Two periods of dietary intervention, each at least five weeks in duration: 1) a chickpea-supplemented diet and 2) a wheat-supplemented diet.  Chickpea diet involved daily consumption of 140g of canned, drained chickpeas, chickpea bread, and chickpea shortbread biscuits provided by study personnel.  Wheat diet involved consumption of whole meal (wheat) bread, high-fiber (wheat) breakfast cereals and shortbread biscuits that participants purchased from their usual grocery store.  Measurements: Serum TC, LDL-C, HDL-C and TAG.	NS differences in body weight and BMI between the start and end of each dietary period or at end of the two intervention diets (all P>0.2).  Serum lipids and lipoproteins NS different at the start of intervention diets.  PRO (0.9% of energy, P=0.01) and MUFA (3.3% of total fat, P<0.001) intakes were slightly but significantly ↓ and CHO intake significantly ↑ (1.7% of energy, P<0.001) on the chickpea diet as compared with wheat diet.  Serum TC was 3.9% ↓ (0.22mmol per L; 95% CI: 0.1, 0.35; P=0.001) and LDL-C was 4.6% ↓ (0.18mmol per L; 95% CI: 0.07, 0.29; P=0.002) at the completion of the chickpea diet as compared with wheat diet.  Multivariate analyses suggested that differences in serum lipids were mainly due to small differences in serum lipids were mainly due to small differences in PUFA and dietary fiber contents between the two intervention diets.  Serum HDL-C and TAG levels NS different between the two intervention diets.

Pittaway JK et al 2007

Study Design: Randomized Crossover Trial

Class: A

Rating:

N=31 subjects (mean age 50.6±10.5 years) enrolled in the trial

N=27 (17 female, 10 male) completed both diet interventions and 18 (11 female, 7 male) completed the lower fiber diet study.

Location: Australia.

Compared effects on serum lipids, glucose tolerance, satiety and bowel function of a diet supplemented with chickpeas to a wheat-based diet of similar fiber content and also impact of a lower fiber diet on bowel function and satiety.

Subjects consumed two dietary interventions for five weeks each, with a washout period of six to eight weeks between interventions; the additional low fiber diet study followed for three weeks only.

Chickpea diet based on consuming 140g of canned, drained chickpeas daily, plus bread and shortbread biscuits made with 30% chickpea flour.

Wheat diet based on consuming whole wheat bread and ↑ fiber breakfast cereals daily, while lower fiber diet included white bread and lower fiber breakfast cereals.

Compared to wheat diet, chickpea diet resulted in ↓ in serum TC of 0.25mmol per L (P<0.01) and LDL-C of 0.20mmol per L (P=0.02), while NS differences in glucose tolerance.

Some participants reported a perceived improvement in general bowel health and greater satiety during chickpea diet.

Pittaway JK et al 2008

Study Design: Ordered Crossover Trial

Class: C

Rating:

N=50 subjects (mean age 52.2±6.1 years) enrolled and 45 (13 pre-menopausal women, 19 post-menopausal women and 13 men) completed the trial.

Location: Australia.

Observed effects of chickpea supplementation on ad libitum nutrient intake, body weight, serum lipids, lipoproteins and other metabolic  $\Delta$ .

Subjects consumed normal intake for four weeks, ad libitum diet with at least 104g of chickpeas per day for 12 weeks, and normal

During the chickpea phase, mean dietary fiber intake was 6.77g per day  $\uparrow$  and mean PUFA consumption was 2.66%  $\uparrow$  (P<0.001), causing the PUFA to SFA ratio to  $\Delta$  from 0.39 to 0.47 (P=0.045).

Serum TC  $\downarrow$  by 7.7mg per dL (0.20mmol per L) and L DL  $\downarrow$ C  $\downarrow$  by 7.3mg per dL

LDL-C \ Uy 1.5mg pci uL intake for four weeks. (0.19mmol per L) after the chickpea phase (both P<0.01). In addition, fasting insulin  $\downarrow$  by 0.75µIU per ml (0.19mmol per L) and homeostasis assessment model of insulin resistance was  $\downarrow$  by 0.21 (both P=0.01). Dietary fiber had the greatest single effect, \( \) serum TC by 15.8mg per dL (0.41mmol per L, P=0.01). Steffen LM et Participants from the Evaluated associations of Over 15 years, 23.2% of al 2005 study participants Coronary Artery Risk dietary intake with 15-year Development in incidence of elevated experienced incident EBP Young Adults (defined as incidence SBP blood pressure (EBP). Study Design: Prospective (CARDIA) Study. >130mmHg, DBP Dietary intake measured at Cohort Study >85mmHg, or the use of Out of 5,115 baseline and year seven, antihypertensive participants (aged 18 while clinic exams were Class: B medications); 591 (13.7%) to 30 years at scheduled at baseline and had HTN and 406 (9.4%) baseline) in the years two, five, seven, 10 had high-normal BP. Of Rating: original cohort, 4,304 and 15. those who developed EBP, participants were 64% were black men and Dietary intake assessed included in analysis women. (883 black men, 1,249 interviewer-administered black women, 989 After adjustment for diet history. white men and 1,183 confounding variables, white women). plant food intake (whole grains, refined grains, fruits, Location: United vegetables, nuts and States. legumes) inversely related to EBP. Concerning specific plant subgroups, whole grain, fruit and nuts inversely associated with EBP  $(P \le 0.05)$ , whereas no association observed with refined grains, vegetables or

legumes. Tertiles of legume intake were < 0.1, 0.1 to 0.2 and >0.2 times per day. HR for legume intake from tertiles one through three were 1.00, 0.93 (95% CI: 0.80, 1.09) and 0.88 (95%) CI: 0.75, 1.03; P=0.11). Authors noted that limited consumption of legumes and insufficient statistical power precluded definitive conclusions from being drawn. Unclear whether null findings were due to lack of association or limited range in consumption. Welty FK et al Hypertensive Determined effect of soy Compared with TLC diet 2007 (SBP>140mmHg), nuts on SBP and DBP and alone, TLC diet with soy nuts ↓ SBP by 9.9% pre-hypertensive lipid levels. (P=0.003) and DBP by Study Design: (SBP 120 to After a four-week run-in Randomized 139mmHg) and 6.8% (P=0.001) in period. Crossover Trial normotensive hypertensive women, 5.5% women randomized to (P=0.003) and 2.7%(SBP<120mmHg) eight weeks of a TLC diet Class: A post-menopausal (P=0.18) in alone and eight weeks of a women. pre-hypertensive women, TLC diet of similar and 4.5% (P=0.003) and Rating: N = 60energy, fat and PRO 3.0% (P=0.06) in women included in content in which 1/2 cup normotensive women. the trial: unsalted soy nuts (25g soy PRO, 101mg aglycone In addition, soy nut 48 isoflavones) replaced 25g supplementation ↓ LDL-C normotensive, of non-soyPRO, with a by 11% and apolipoprotein mean age four-week washout B levels by 8% (P=0.04 for 53.5±5.3 years between diets. both) in hypertensive • 12 hypertensive, women, but no effect in mean age normotensive women 58.3±6.5 years. No  $\Delta$  in TC, HDL-C, Location: United or TG observed in any States group.

### **Research Design and Implementation Rating Summary**

For a summary of the Research Design and Implementation Rating results, click here.

### Worksheets

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